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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,328	04/25/2005	Klaus Cichutek	GRUND-101	6255
2387	7590	08/18/2008		
Olson & Cepuritis, LTD. 20 NORTH WACKER DRIVE 36TH FLOOR CHICAGO, IL 60606			EXAMINER MARVICH, MARIA	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 08/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,328	Applicant(s) CICHUTEK ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9,11-15,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 11-15, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/18/07 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 2, 4-9, 11-15, 18 and 19 are pending in this application. This office action is in response to an amendment filed 5/8/08.

Claim Objections

Claims 6, 8 and 9 are objected to because of the following informalities: in claim 6, the recitation “a gene capable of expressing” is inaccurate as a gene does not express a protein but is expressed from a promoter into mRNA which is then translated into a protein. It would be proper to amend this phrase to recite --a gene encoding—and --wherein the gene is under control of a promoter--.

The preamble of claim 9 should be amended to recite --method for making pseudotyped SIVsmmPBj14 vector--. First, the method only yields a single vector. Secondly, the method only leads to production of pseudotyped SIVsmmPBj14 vectors and not any pseudotyped vectors. In addition to this amendment the article “a” in line 3 prior to “SIVsmmPBj14 should be amended to --the--.

Claim 8 recites “the envelope protein”. However, there are two envelope proteins encompassed by the claims, that from SIVsmmPBj and the other from the group recited in claim 7. It is unclear whether the claim is drawn to the SIVsmmPBj envelope protein or the non SIVsmmPBj envelope protein. Hence it would be clearer if the claim indicated --the non SIVsmmPBj envelope protein--. Applicants argue that the rejection but based upon the lack of clarity as to whether the envelope protein is the G-protein of VSV or of SIVsmmPBj, the claim is

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rejected. As presently recited, the vector is a retroviral vector, which encompasses retroviral vectors.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-9, 11-15, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pseudotyped pSIVsmmPBj vector in which the SIVsmmPBj14 virus envelope gene is not expressed wherein the vector can transduce cells in a G₀ phase, a mitotic phase and a G₁ phase, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This is a new rejection.**

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The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a retrovirus or lentivirus comprising a deletion in the env gene of SIVsmmPBj14 or SIVsmmPBj1.9 such that the envelope protein is not expressed. Claim 1 also recites that the vector can transduce cells in a G₀ phase. Claims 18 and 19 are drawn to a lentivirus comprising a SIVsmmPBj1.9 lentivirus comprising an inactive *env* gene wherein the virus is capable of transducing cells in a G₀ phase. While the claim recite the functional property of a vector that can transduce cells in a G₀ and a mitotic and/or G₁ phase, the structural requirements of a large group of lentivirus and/or retroviruses that mediate such function are unknown. The specification teaches that SIVsmmPBj14 viruses are part of the subgroup of lentivirus, which forms the larger group of retrovirus. They were isolated from Sooty Mangabey monkeys and were found to be capable of replicating in non-stimulated primary human lymphocytes in the G₀ phase. Whereas "all known lentiviral-derived vectors are suitable for use in non-proliferating cells having a certain kind of activation status, namely, in the G₁-phase of the cell cycle. Applicants have generated a recombinant SIVsmmPBj14 virus comprising a VSV-G env protein and tested the ability of this vector to infect a variety of human cell lines arrested at G₀ and G₁.

The claims are so broad as to read on a variety of non-enabled compositions. First, the recited vector is recited as being any retrovirus vector or any lentivirus vector. However, the claims recite components that limit the vector to one that is primarily a SIVsmmPBj vector based upon either SIVsmmPBj14 or SIVsmmPBj1.9. Furthermore, by recitation in claims 1, 2 and 18 that the vector “is capable of transducing cells in a Go phase” and “is further capable of transducing cells in a mitotic phase and/or G₁ phase” inherent properties of a vector based upon SIVsmmPBj is recited that are not present in the entirety of the retroviral or lentiviral family. Secondly, the limitation in claim 2 is not further limiting of the vector components recited in claim 1. Third, such a SIVsmmPBj vector lacking any envelope proteins would not be able to transduce any cells. An envelop protein is required and while it need not be strictly from SIVsmmPBj, there must be an envelope protein present. Hence, the limitations of claim 5 are required. Claim 6 describes pseudotyping by expression of a gene encoding a heterologous envelope.

The invention recites use of a broad genus of viruses. Given the unpredictability of the art, the poorly developed state of the art with regard to predicting the structural/ functional characteristics of viruses derived from SIVsmmPBj14 virus as well as env deletions for pseudotyping, the lack of adequate working examples and the lack of guidance provided by applicants, the skilled artisan would have to have conducted undue, unpredictable experimentation to practice the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

/Maria B Marvich, PhD/
Primary Examiner, Art Unit 1633